

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New)
Rules I through VI pertaining to the)
medical marijuana program)

NOTICE OF PUBLIC HEARING ON
PROPOSED ADOPTION

TO: All Concerned Persons

1. On October 17, 2008, at 1:30 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room of the Colonial Building, at 2401 Colonial Drive, Helena, Montana, to consider the proposed adoption of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Department of Public Health and Human Services no later than 5:00 p.m. on October 6, 2008, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 202951, Helena, Montana, 59620-2951; telephone (406)444-9503; fax (406)444-6744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I DEFINITIONS In addition to the terms defined in 50-46-102, MCA, the following definitions apply to this chapter:

- (1) "Adult applicant" means a qualifying patient of 18 years of age or older.
- (2) "Applicant" means an individual applying for registration in the Montana Medical Marijuana Program.
- (3) "Approved patient" means a qualified patient who is on the program registry and has been issued a registry identification card.
- (4) "Attending physician" means a Doctor of Osteopathy or medical doctor who has established a bona fide physician/patient relationship with the applicant, is licensed under Title 37, chapter 3, MCA, and who, with respect to an applicant diagnosed with a debilitating medical condition:
 - (a) is primarily responsible for the medical care and treatment of the applicant;
 - (b) has reviewed the applicant's medical records at the request of the applicant;
 - (c) has conducted a thorough physical examination of the applicant;
 - (d) has provided or planned follow-up care; and
 - (e) has documented these activities in the applicant's medical record.

(5) "Bona fide physician/patient relationship" means a physician/patient relationship made in good faith without fraud or deceit and is sincere with earnest and wholehearted intent.

(6) "Minor applicant" means a qualifying patient less than 18 years of age.

(7) "Registry" means the department's Medical Marijuana Program confidential listing of approved patients and approved caregivers.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE II REGISTRATION AND APPLICATION PROCESS (1) An adult applicant, or a parent or guardian of a minor applicant, must have a Montana mailing address and submit an application form provided by the department for consideration to be placed in the state's confidential medical marijuana registry. An application form is available by contacting the Department of Public Health and Human Services, Licensure Bureau, 2401 Colonial Drive, Helena, MT 59620-2925. Application forms are also available on the department's web site at www.dphhs.mt.gov.

(2) Application materials that must be provided include:

(a) application fee;

(b) the applicant's name, address, date of birth, social security number, or state of Montana identification (ID) number;

(c) the name, address, date of birth, and social security number or state of Montana ID number of the applicant's designated caregiver, if any;

(d) the attending physician's signed and dated statement which includes their name, address, telephone number, Montana medical license number, and written certification attesting to the attending physician's diagnosis that the applicant has a debilitating medical condition as defined in 50-46-102, MCA.

(3) A copy of the relevant portions of an applicant's medical record may serve as the attending physician's written certification as long as it clearly states:

(a) the patient has been diagnosed by the attending physician with a qualifying debilitating medical condition;

(b) the medical use of marijuana may mitigate the symptoms or effects of the debilitating medical condition; and

(c) the date the medical record was made and the attending physician's signature.

(4) The signed and dated attending physician's statement or copies of chart notes or medical records must be current within three months of the date of an applicant's new or renewal application.

(5) The department will verify with the Montana Board of Medical Examiners that the attending physician is licensed to practice in the state of Montana, is currently on active status, and the license is in good standing.

(6) If the applicant wants to use a caregiver, a caregiver must be designated on the application. The caregiver must sign a statement agreeing to provide medical marijuana only to those qualifying patients who have designated on their application that individual as their caregiver.

(7) The department will conduct a name-based criminal background check using the Montana Criminal Justice Information Network to verify that a person designated to be a caregiver has not been convicted of a felony drug offense in accordance with 50-46-103, MCA.

(8) The department will issue a registry identification card to an approved caregiver for each approved applicant who lists them as their caregiver.

(9) The department will either approve or deny an application within 15 working days of receipt of the application. If approved, the department shall issue a registry identification card to the applicant within five working days of approving the application.

(10) The registry identification card expires one year from the date of issuance and may be renewed.

(11) If the application is denied, the department will send the applicant notice of this denial and inform the applicant the reasons for denial.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE III INVALIDATION OR REVOCATION OF REGISTRY IDENTIFICATION CARD (1) An approved patient who no longer has a debilitating medical condition and their approved caregiver, if any, shall return all registry identification cards to the department within ten days of the patient receiving written diagnosis by the approved patient's attending physician. It is the responsibility of the cardholder to return the registry identification card.

(2) A registration card is not valid if the card has been altered or mutilated in a way that impairs legibility. A photocopy of a registry identification card is not valid.

(3) The department may revoke an approved caregiver's registry identification card if the department determines that an approved caregiver has violated the provisions of this chapter or the Montana Medical Marijuana Act.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE IV FEES (1) The application fee is \$50.
(2) The annual renewal fee is \$50.
(3) All fees:
(a) must be submitted with the application;
(b) must be paid by check or money order made payable to the Department of Public Health and Human Services; and
(c) are nonrefundable unless the applicant is denied.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE V CHANGE OF CAREGIVER (1) Caregiver changes may be initiated no more than two times in a 12-month period unless extenuating

circumstances exist. Such circumstances may include, but are not limited to, the following:

- (a) death of an approved caregiver;
 - (b) documented family discord, if the approved caregiver is considered a family member; or
 - (c) approved caregiver relocation to another area and can no longer serve the approved patient.
- (2) When changes are requested, the department must be notified in writing of the changes, including:

- (a) new caregiver, if designated;
- (b) adding a caregiver if no caregiver previously designated; or
- (c) removing current caregiver with no replacement assigned.

(3) The department shall process any change of caregiver requests within ten working days of receipt of a written request.

(4) Upon receipt of a change of caregiver request, the department will notify the cardholders in writing regarding the termination date of their registry identification cards. When a change in approved caregiver occurs, both the approved patient and previously approved caregiver must destroy their registry identification card.

(5) Upon approval of the written change request, the approved patient and new approved caregiver, if designated, must be sent a new registry identification card and correspondence listing the effective date of the approved caregiver change.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE VI REPLACING LOST OR STOLEN REGISTRY

IDENTIFICATION CARDS (1) If a program registry identification card has been lost or stolen, the department must receive written notification from the approved patient or the approved caregiver prior to replacing the registry identification card.

(2) If the registry identification card has been lost or stolen, the department will advise the approved patient or approved caregiver to notify local law enforcement.

(3) Upon receipt of notification by the cardholder, the department will reissue as duplicate the registry identification card and send it to the approved patient or approved caregiver.

(4) The approved patient's file will include the notification regarding the lost or stolen card and duplicate registry identification card reissue information.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

4. On November 2, 2004, Initiative I-148 (otherwise known as the Montana Medical Marijuana Act) was approved by 62 percent of Montana voters. The Department of Public Health and Human Services was the designated agency to develop and implement a program in which qualified patients and identified caregivers were confidentially "registered" under the Montana Medical Marijuana

Act. In early 2005, the department issued the first Medical Marijuana Program registry identification cards.

The Legislative Audit Division performed an audit of the Montana Medical Marijuana Program during the summer of 2007. The Legislative Audit Division recommended that the department develop rules to establish fees as required under 50-46-210, MCA.

As a result, the department has prepared a proposed rule package based on existing policy pertaining to the Medical Marijuana Program. The rules contained in this package address the statutory mandate to develop an administrative process for the initial application and subsequent renewal of registry identification cards for qualifying patients and caregivers. Further, the rules establish application and renewal fees that generate revenue sufficient to offset all expenses of implementing and administering the requirements under the Act.

There is no other option for meeting the mandate of 50-46-210, MCA, therefore the department is proposing New Rules I through VI to address the manner in which the department will consider applications for and renewals of registry identification cards for qualifying applicants and caregivers.

The department is proposing New Rule I to define terms used in conjunction with the program not defined in 50-46-102, MCA. Defining the terms provides clarification to applicants, caregivers, physicians, the general public, and department staff.

New Rule II is proposed to place in administrative rule the process which the department has been using to implement the Montana Medical Marijuana Act. Through the provisions of the Act, the department has developed policies and procedures to implement and administer the Act. Due to the specificity of the Act and until the previously mentioned legislative audit, the department felt it was unnecessary to promulgate rules. The department concurred with the Legislative Audit Division's recommendation to promulgate rules, and therefore proposes this rule to address the registration and application process. The application form must contain enough unique identifying information to adequately identify applicants and caregivers.

The department is proposing New Rule III to clarify the impact of a written diagnosis that an approved patient no longer has a debilitating illness, as well as to clarify when the department may revoke a caregiver registry identification card. In the event an approved patient's diagnosis changes, this rule reinforces that the patient no longer meets the conditions necessary for possession of a registry identification card or placement on the registry.

New Rule IV is proposed in response to the recommendation of the Legislative Audit Division. When the department implemented the program, the initial fee charged was \$200. The department reduced the fee to \$100 six months after implementation and the fee was reduced to \$50 on July 1, 2006. It is anticipated that an average of

300 qualifying patients per year will be approved for the program generating \$15,000 in revenue and \$39,050 will be generated from 781 approved patient renewals.

New Rule V is proposed to identify the process for changes in caregiver. Either the approved patient or approved caregiver can terminate the patient/caregiver relationship. This rule is necessary to minimize the number of times this relationship may be changed. When an approved patient designates a caregiver on an application, when approved, that caregiver can then grow up to six marijuana plants for each approved patient that has designated that individual as caregiver. If this relationship terminates, the caregiver could have six marijuana plants for an approved patient where a patient/caregiver relationship no longer exists. Minimizing the number of times the approved patient/caregiver relationship can be terminated during a 12-month period prevents unnecessary changes in caregivers, protects the caregiver from having to destroy plants too often thereby creating a financial burden, minimizes the time caregivers have plants with no approved patients, yet allows the approved patient the flexibility to maintain a satisfactory patient/caregiver relationship.

The rule is also necessary to remove from the registry those caregivers who are no longer approved caregivers. These provisions help ensure than an approved patient has only one caregiver as authorized by 50-46-102, MCA.

The department is proposing New Rule VI to identify the process for replacing registry identification cards because the registry identification card protects the approved patient and approved caregiver for the medical use of marijuana. It is in the best interests of both the patient and caregiver to notify the department as soon as possible regarding the loss or theft of a registry identification card.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 202951, Helena, Montana, 59620-2951; telephone (406) 444-9503; fax (406) 444-9744; or e-mail dphhslegal.mt.gov, and must be received no later than 5:00 p.m., October 23, 2008.

6. Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 5 above or may be made by completing a request form at any rules hearing held by the department.

8. An electronic copy of this Proposal Notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of the Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

9. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

s/ Lisa Swanson
Rule Reviewer

/s/ Russell E. Cater for
Joan Miles, Director
Public Health and Human Services

Certified to the Secretary of State September 15, 2008.